CABINET FOR HEALTH AND FAMILY SERVICES
DEPARTMENT FOR PUBLIC HEALTH

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Audrey Tayse Haynes
Secretary

To: All Kentucky Vaccine Program (KVP) **VERY IMPORTANT!**

From: Laura Harrod, MS Ed
Kentucky Vaccine Program Coordinator

Date: March 1, 2013

Subject: KVP Update Concerning **MANDATORY** Changes in KVP Policies and Procedures

The Office of Inspector General (OIG) of the US Department of Health and Human Services conducted a review of Federal and State Vaccine for Children (VFC) Programs and released their findings in a report to the Centers for Disease Control and Prevention (CDC) in 2012. The OIG findings require improved accountability and practice from Federal and State VFC Programs in regards to vaccine supplies and storage of vaccines by providers. In response to the OIG report, CDC is implementing mandatory policy changes for all VFC Programs and Vaccine Program (KVP) providers. Providers found in non-compliance with these changes will be suspended from the program until compliance is achieved. The changes and timeline for compliance are described in the attached four page document, **2013 Kentucky Vaccine Program Mandatory Changes**. Other attachments are provided for reference and your convenience.

The complete OIG report may be found at: https://oig.hhs.gov/oei/reports/oei-04-10-00430.asp

Again, the listed changes are mandatory for all KVP providers. Please, contact KVP staff for questions or concerns regarding this memo at (502) 564- 4478. Our phone extensions have recently been updated and are listed below.

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2013 Kentucky Vaccine Program Mandatory Changes

ADMINISTRATIVE CHANGES: No cost associated with change

RECOMMENDED:

1. **Change in KVP administration fee:**
   The administration fee for KVP supplied vaccines has increased from $14.17 to $19.93 per dose. All non-Medicaid (or non-Medicaid Managed Care Organization) VFC eligible patients may be charged up to and not over $19.93 per dose. This change may be implemented immediately.

REQUIRED:

2. **Changes to your office contact personnel for KVP, including anyone that receives or stores KVP vaccines, MUST be communicated to the KVP central office immediately.**
   KVP must be notified immediately of changes in provider's personnel involved with any aspect of KVP vaccine. New personnel must complete required KVP training. This change is effective immediately.

3. **All changes of address must be reported to KVP immediately. KVP must be notified prior to physical/location moves of practices.**
   Failure to notify KVP will result in provider suspension. This change is effective immediately.

4. **Patient eligibility must be checked and recorded for each vaccination visit to ensure status has not changed. Documentation of eligibility screening must be available to KVP upon request.**
   This is not a new requirement, but a reminder to providers. (CDC approved Patient Eligibility Screening Record enclosed/attached)

   Kentucky is a universal Hepatitis B birth dose state. Infants born in Kentucky hospitals may receive a dose of Hepatitis B vaccine after birth.

   Hospitals enrolled in KVP will receive Hepatitis B vaccine and Hepatitis B Immune Globulin when indicated. These hospitals must assess eligibility during mothers' registration. This information is required on the Hospital Vaccine Order Form.

5. **Underinsured patients (i.e., patients with insurance that does not cover vaccines or a patient whose insurance covers selected vaccines only) may only receive KVP vaccines at Federally Qualified Health Centers (FQHCs), Rural Health Centers (RHCs), and Health Departments that have delegated authority from a FQHC or RHC (This includes all Kentucky Health Departments with the exception of Fayette County Health Department).**
   Kentucky implemented this mandatory change for all providers in February 2012.

6. **New KVP Providers will follow all CDC Vaccine Storage and Handling Interim Guidance.**
   This guidance is located at: http://www.cdc.gov/vaccines/recs/storage/interim-storage-handling.pdf.
   (Copy enclosed/attached)

2013 Kentucky Vaccine Program Mandatory Changes

7. **Providers are required to review expiration dates of KVP vaccine and rotate KVP stock weekly.** Continue using your current temperature log and record the dates vaccine expiration as assessed. Expired vaccine should immediately be removed from stock, reported to KVP within a week, and returned to McKesson within 6 months. This change is effective for all KVP providers.

   Upon discovering expired vaccines, remove them from stock and complete a Return and Adjustment (R&A) form. A copy of the R&A should be enclosed with the vaccine to be returned, a copy should be retained in the provider's clinic records, and a copy should be sent to KVP. KVP will contact McKesson on your behalf. McKesson will supply a return label to the provider for excise tax credit and for use in returning vaccine. (Copy of "What Not to Return to McKesson" and R&A form attached/enclosed: the R&A Form must be used for all returns, transfers, wasted vaccines, etc.)

8. **All providers will store vaccine according to CDC Interim Guidelines: in a manner that allows adequate circulation of air and appropriate thermometer placement.**
   This is required of all KVP providers. Information on best storing practices is included in the CDC Storage and Handling Toolkit. (Copy of California Department of Public Health "Vaccine Storage" handout attached/enclosed)

9. **At a minimum, the VFC Coordinator (previously known on the enrollment form as the Primary Vaccine Shipping Contact) must complete storage and handling training at the yearly site visit. The training will be documented on the CDC portion of the enrollment form.**
   All new providers enrolling in the KVP program must complete training before being accepted into the program. This change became effective January 1, 2013.

   All existing providers will receive a VFC Compliance visit from our field staff. The on-site education provided during that site visit will serve as the storage and handling training for the year.

   It is *recommended* but not required for the Back-Up VFC Coordinator to attend the yearly on-site education with field staff or review the CDC VFC Requirements *You Call The Shots* and Storage and Handling *You Call The Shots* modules to support meeting the provider education component. The modules produce a certificate of completion. The modules can be found at:
   http://www.cdc.gov/vaccines/ed/youcalltheshots.htm

2013 Kentucky Vaccine Program Mandatory Changes

KVP CHANGES – Potential for associated cost

REQUIRED:

1. **Unannounced storage and handling assessment visits.**
   Unannounced visits are separate from VFC Compliance Visits or as follow up performed as part of a corrective action plan. These visits will serve as a "spot check" for proper storage and handling practices. The goal of the unannounced visits is to provide guidance and education on proper storage and handling, thus ensuring that all VFC eligible children are receiving properly managed vaccines. Not all but some providers will receive an unannounced visit. These visits are mandatory and will become effective immediately.

2. **Current KVP providers must work toward following "CDC Vaccine Storage and Handling Interim Guidance".**
   Current refrigerators, freezers and thermometers will be allowed, or "grandfathered" in, as long as the thermometers are certified and calibrated (see below). Also, there should be no past temperature excursions, loss of vaccine or address moves.

   Existing providers will be required to replace household single-condenser combination units when they become defective. Refrigerators and freezers should be replaced with stand-alone units. Field Staff must assess units before receiving vaccine if the office location is moved to another site. Dorm style units may not be used for any reason for storage of VFC vaccine.

   This guidance is intended for use by all public and private sector providers; and, while recognizing that cost may be a barrier, we encourage practices to move toward implementing these recommendations as soon as possible. CDC is currently evaluating the most efficient and cost effective method to phase these recommendations in and more guidance is forthcoming.
   CDC Vaccine Storage and Handling Guidelines located at:
   http://www.cdc.gov/vaccines/recs/storage/interim-storage-handling.pdf (Copy of guidance enclosed/attached)
   CDC revised Vaccine Storage and Handling Toolkit November 2012 located at:
   http://www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf
   This change is effective immediately.

3. **CDC *recommends* thermometers with the following characteristics:**
   a. Provide continuous monitoring information with an active display.
   b. Include an alarm for out-of-range temperatures.
   c. Have a reset button if using a data logger with a min/max display.
   d. Be capable of showing current temperature as well as minimum and maximum temperatures.
   e. Be within +/- 0.5°C accuracy (+/-1°F).

      (1) **All Kentucky providers are required to have a calibrated certified thermometer.** A copy of the certificate(s) must be given to the Field Staff at the VFC Compliance Site Visit and/or unannounced office visits. If a certified calibrated thermometer does not have an expiration date written on the certificate, the certificate is approved for one year of use.

(2) When purchasing a new thermometer, providers are expected to purchase a thermometer that meets the CDC recommended guidelines above. The Kentucky Immunization Program does not have a brand preference.

4. **Dorm style refrigerators are not allowed for KVP vaccine storage and must be replaced immediately. (This includes temporary storage).**
   All existing KVP providers have discontinued use of dorm style refrigerators for permanent storage. Sites utilizing dorm style refrigerator for temporary storage of KVP vaccines, must cease this activity immediately and vaccine moved to appropriate storage. (A dorm style refrigerator is defined as a small combination refrigerator-freezer unit that is outfitted with one external door and an evaporator plate or cooling coil which is located inside an icemaker compartment or freezer within the refrigerator. Size does not make a unit a dorm style.)

5. **CDC recommends use of stand-alone refrigerator and stand-alone freezer units suitable for vaccine storage rather than combination (refrigerator + freezer) or other units not designed for storing fragile biologics.**
   New providers are required to have separate stand-alone vaccine storage before enrolling in the KVP program. These units are not required to be "regular household" size units but can be a smaller under the counter style.

   Existing providers are required to replace combination units when they become defective. Refrigerators and freezers should be replaced with stand-alone units. Field Staff must assess units before receiving vaccine if the office location is moved to another site. (This information may change as CDC revises/updates their requirements.) ("3 Easy Steps to Buy a Refrigerator or Freezer" enclosed/attached)

6. **Temperatures must be checked and recorded twice daily regardless of types of storage units and/or thermometers.**
   This is not a new requirement and is already effective. In the future KVP will follow the CDC recommendation to check and document the minimum/maximum temperature once per day preferably in the morning.

Attachments (6)

1. Patient Eligibility Screening Record
2. CDC Vaccine Storage and Handling Interim Guidance
3. Return and Adjustment Form, revised 2/13
4. What Not To Return to McKesson
5. "Vaccine Storage" handout from the California Department of Public Health
6. 3 Easy Steps To Buy A Refrigerator Or Freezer

Patient Eligibility Screening Record
Vaccines for Children Program

1. Initial Screening Date: (_ _ / _ _ / _ _ _ _)
   M M D D Y Y Y Y

2. Child's Name: _____ _____ _____
   Last Name First MI

3. Child's Date of Birth: (_ _ / _ _ / _ _ _ _)
   M M D D Y Y Y Y

4. Parent/Guardian/Individual of Record: _____ _____ _____
   Last Name First MI

5. Is your facility a Federally Qualified Health Center (FQHC) or Rural Health Clinic (RHC)?

   ☐ Yes ☐ No

6. Primary Provider's Name: _____ _____ _____
   Last Name First MI

7. Does this patient qualify for immunization through the VFC program because he/she (check only one box):
   - a) Yes, is enrolled in Medicaid ☐
   - b) Yes, does not have health insurance ☐
   - c) Yes, is an American Indian or Alaska Native ☐
   - d) Yes, is underinsured (has health insurance that does not pay for vaccinations)* ☐
   - f) No, this child does not qualify for immunizations through the VFC program because he/she does not meet the eligibility criteria. ☐

Current Eligibility Status					
Date	Is enrolled in Medicaid	Does not have health insurance	Is an American Indian or Alaska Native	Is underinsured (has health insurance that does not pay for vaccinations)*	Does not meet eligibility criteria

A record of all children 18 years of age or younger who receive immunizations must be kept in the health care provider's office. The record may be completed by the parent, guardian, individual of record, or by the health care provider. **VFC eligibility screening and documentation of eligibility status must take place with each immunization visit to ensure the child's eligibility status has not changed.** While verification of responses is not required, it is necessary to retain this or a similar record for each child receiving vaccine.

** To be supported with VFC purchased vaccine, underinsured children must be vaccinated through a FQHC or RHC or under a deputized agreement with an approved provider.*

Vaccine Storage and Handling

INTERIM GUIDANCE

Introduction

In response to recent scientific studies[1] on equipment used for vaccine storage and a better understanding of best practices for vaccine storage and handling, the Centers for Disease Control and Prevention (CDC) is providing interim guidance on appropriate vaccine storage and handling practices. This guidance is intended for use by all public and private sector providers and, while recognizing that cost may be a barrier, we encourage practices to move toward implementing these recommendations as soon as possible. CDC is currently evaluating the most efficient and cost effective method to phase these recommendations in and more guidance is forthcoming.

With the goal of improving the way providers store and handle vaccines nationwide, several important changes have been made to previous recommendations issued by CDC, including:

1. Use of a biosafe glycol-encased probe or a similar temperature buffered probe rather than measurement of ambient air temperatures, and;
2. Use of digital data loggers with detachable probes that record and store temperature information at frequent programmable intervals for 24 hour temperature monitoring rather than non-continuous temperature monitoring, and;
3. Use of stand-alone refrigerator and stand-alone freezer units suitable for vaccine storage rather than combination (refrigerator+freezer) or other units not designed for storing fragile biologics, such as vaccines, and;
4. Discontinuing use of dorm-style or bar-style refrigerator/freezers for ANY vaccine storage, even temporary storage, and;
5. Weekly review of vaccine expiration dates and rotation of vaccine stock.

More detail regarding these changes and the rationale behind them is included below.

Biosafe Glycol-Encased Probes or Similar Temperature Buffered[1] Probes

CDC recommends use of a digital thermometer with a biosafe glycol-encased probe or a similar temperature buffered probe that will more closely approximate the measure of liquid temperature. A temperature buffer enables a thermometer probe to more closely match the temperature changes experienced by stored vaccine. Examples of temperature buffers are a probe inserted into a glycol-filled vial or one inserted into glass beads. CDC recommends this type of probe because studies by the National Institutes of Standards and Technology (NIST), U .S. Dept of Commerce [1] conducted in 2009 showed that compared to temperature monitors that measure ambient air temperature, the digital thermometer with glycol-encased probe more accurately reflects the temperature of the vaccine vial and does not register normal air temperature fluctuations which do not significantly impact vaccine temperature. Because the main factor affecting potency of refrigerated vaccines is exposure to freezing temperatures, it is important that glycol-encased or similar temperature buffered probes be placed among the vaccines instead of on a wall, and at least for refrigerated vaccines, in the part of the refrigerator unit where manufacturer recommended vaccine storage temperatures can best be maintained. To ensure validity of temperature measurements, only calibrated thermometers with a certificate of Traceability and Calibration should be used. Calibrated thermometers will continue to be a requirement for providers who receive VFC vaccine.

Digital Data Loggers for Temperature Monitoring

In addition to the use of a digital thermometer with a biosafe glycol-encased or similar temperature buffered probe, the thermometer should also be able to provide and store data monitoring information set at programmable intervals in an active display that allows for reading temperatures without opening the unit door. This means that the digital data logging thermometer probe should be able to remain in place and not be disturbed during data reading and recording. A detachable probe facilitates downloading temperature data without removing the probe from the storage unit, and should simplify daily use and minimize operator cause of temperature variability. The digital data logger should also include the following:

- Hi/Lo alarm for out-of-range temperatures;
- Current temperature, as well as minimum and maximum temperatures;
- Reset button ;

[1] The purpose of a temperature buffer is to slow the response time of the probe to temperature changes so that it matches the temperature changes experienced by the vaccine.

- Low battery indicator;
- Accuracy of +/- 1°F (0.5°C);
- Memory storage of at least 4000 readings, device will not rewrite over old data and stops recording when memory is full;
- User programmable logging interval (or reading rate).

These changes in the use of systems for continuous temperature monitoring mean more accurate and comprehensive monitoring of any temperature excursions to which vaccines may have been exposed, and diminish the need for opening the unit door while conducting this routine monitoring. Finally, it is a requirement for VFC providers and a recommendation for all providers that storage unit temperatures continue to be read and documented twice each workday. It is recommended that minimum/maximum temperatures be checked and documented once per day preferably in the morning. Reviewing the minimum/maximum temperatures helps to ensure that temperature excursions will be identified more quickly and corrections made that can prevent vaccine loss, as well as minimize the inaccuracy of generalizing twice daily measurements.

Stored temperature monitoring data should be downloaded and reviewed at least weekly by providers, both to ensure the timely review of the data and the appropriate response to issues. When the data is downloaded, the data logger should be reset so there is sufficient memory available. The downloaded information should be kept for a minimum of 3 years or according to individual state record retention requirements. These practices ensure that the data logger will continue to function properly with sufficient memory for accurate monitoring and that problems with storage equipment can be identified and corrected early.

Stand-Alone Refrigerator and Stand-Alone Freezer Units

CDC strongly recommends the use of stand-alone refrigerator and stand-alone freezer units, meaning a self-contained unit that only refrigerates or freezes and is suitable for vaccine storage. These units can vary in size, from a compact, under-the-counter style to a large, stand-alone, pharmaceutical grade storage unit. CDC does not recommend use of dormitory[2] or bar-style refrigerator/freezers for ANY vaccine storage. The use of these specific refrigerator/freezers is not allowed at any time for Vaccines for Children (VFC) program providers.

[2] Dormitory-style or bar-style refrigerator is defined as a small combination freezer/refrigerator unit that is outfitted with one exterior door and an evaporator plate (cooling coil), which is usually located inside an icemaker compartment (freezer) within the refrigerator. Please note that there are compact, purpose-built storage units for biologics that are not considered to be dormitory-style or bar style.

The characteristics of a recommended storage unit include: 1) enough room to store the year's largest inventory without crowding and 2) sufficient room to store water bottles in the refrigerator and frozen coolant packs in the freezer to stabilize the temperature and minimize temperature excursions that can impact vaccine potency. The addition of water bottles (not gel packs) reduces the risk of freezing due to the tremendous latent heat released from water prior to freezing. In addition, frost-free or automatic defrost cycle units are preferred. Because freezing of refrigerated vaccines affects vaccine potency more than other exposure problems, it is especially important that refrigerators be selected and set up in a way that eliminates the chance of freezing vaccine. Use of stand-alone units is a best practice. Studies by NIST[1] show that 1) dormitory-style or bar-style combination units pose a significant risk of freezing vaccine even when used for temporary storage, and 2) the usual house-hold single-condenser combination refrigerator/freezer units are less capable of simultaneously maintaining proper storage temperatures in the refrigerator and freezer compartments. These refrigerators are cooled by venting cold freezer air into the refrigerated section – thus a real risk of freezing vaccine near the cooling vents. An alternative to stand-alone units is to use only the refrigerator compartment of a combination household refrigerator/freezer unit to store refrigerated vaccines and to be very careful not to use the top shelf if the vent from the freezer opens there. A separate stand-alone freezer should then be used to store frozen vaccines; this is because the freezer compartment of a combined house-hold unit should not be used for vaccine storage if the refrigerator unit is being used for that purpose.

Procedures for Efficient Management of Vaccines

Each provider practice (each location) should have written storage and handling plans, updated annually, both for routine storage and handling of vaccines, and for emergency vaccine retrieval and storage. Plans for routine storage and handling of vaccines should include detailed descriptions of the procedures for: 1) ordering and accepting vaccine deliveries; 2) storing and handling vaccines (e.g., ensuring that refrigerated vaccines are stored between 35°F and 46°F [2°C and 8°C] and frozen vaccines between -58°F and +5°F [-50°C and -15°C]); 3) managing potentially compromised vaccines (i.e., vaccine that has been exposed to temperatures outside of the recommended range defined above); 4) managing vaccine inventory (e.g., checking vaccine and diluent expiration dates weekly and removing expired items from usable stock); and 5) downloading and reviewing electronic monitoring data weekly.

Another necessary component of good practice is ensuring adequately trained vaccination personnel at all levels. This includes personnel that can serve as designated primary and back-up vaccine coordinators, both permanent and temporary staff who are familiar with proper storage and handling policies and procedures, comprehensive storage and handling training for both new staff and maintaining competence of current staff, and accountability checks to ensure protocols are followed. It is also important that a physician partner or member of management is directly involved with the responsible clinical staff – someone with a clear understanding of the vaccine replacement costs of miss-managed refrigerators and vaccine.

Frequently Asked Questions (FAQs) regarding this Interim Guidance are available on our website. The changes summarized in this Interim Guidance will also be reflected in a comprehensive update of CDC's Vaccine Storage and Handling Toolkit (target date for publication Fall 2012). In addition, CDC's posted guidance will continue to be updated as necessary to reflect best practices on vaccine storage and handling. For example, ongoing and planned studies with NIST, U.S. Department of Commerce are being conducted to better understand areas such as optimizing frequency of checking temperature recording by data loggers and packing of vaccine vial boxes for transport.

Thank you and please direct any questions to NIPINFO@cdc.gov

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[i] NISTIR 7656 "Thermal Analysis of Refrigeration Systems Used for Vaccine Storage", Michal Chojnacky, Wyatt Miller, Dean Ripple, Gregory Strouse CSTL November 2009
NISTIR 7753 Michal Chojnacky, Wyatt Miller, Gregory Strouse. Thermal Analysis of Refrigeration Systems Used for Vaccine Storage, PML, September 2010

KENTUCKY IMMUNIZATION PROGRAM VACCINE RETURN & ADJUSTMENT (R&A) FORM

275 EAST MAIN STREET, HS2E-B, FRANKFORT, KY 40621-0001

Phone (502) 564-4478 / Fax (502) 696-4923 / Email: dph.kvp@ky.gov

Pin #: **Phone:** **Date:**

Facility Name:

Address:

Person Preparing Form: **Is this adult or VFC?**

For vaccine spoilage, complete this form along with a plan of correction explaining why the vaccine is wasted and what corrective measures will be taken to prevent future incidents from occurring. Remove expired, spoiled or wasted vaccines from the refrigerator/freezer. Fax both the Return and Adjustment form and the plan of correction to (502) 696-4923. A determination will be made as to whether you will have to replace the wasted vaccine.

Vaccine and NDC #	Lot #(s)	Expiration Date	Number of Doses	Cost Per Dose	Total Cost	Adjustment Code
Vaccine						
NDC #						
Explanation of waste :						
Vaccine						
NDC #						
Explanation of waste :						
Vaccine						
NDC #						
Explanation of waste :						
Vaccine						
NDC #						
Explanation of waste :						
Vaccine						
NDC #						
Explanation of waste :						
Vaccine						
NDC #						
Explanation of waste :						
Vaccine						
NDC #						
Explanation of waste :						
Vaccine						
NDC #						
Explanation of waste :						
Vaccine						
NDC #						
Explanation of waste :						
TOTAL COST OF VACCINE LOST,EXPIRED,WASTED OR SPOILED:						

Name of the site **RECEIVING** vaccine from	**PIN#:**
Address of the site **RECEIVING** vaccine from you:	
Signature of person **RECEIVING** vaccine:	

Revised 2/13

INSTRUCTIONS FOR KENTUCKY VACCINE PROGRAM RETURN AND ADJUSTMENT FORM

Use this form for any adjustments to vaccine inventory. Before returning any vaccine to McKesson or transferring vaccine to another provider, please complete and fax this form to the Kentucky Vaccine Program at (502) 696-4923 or e-mail to dph.kvp@ky.gov.

If transferring vaccines, each provider needs to keep a copy of the completed forms for their records.

VIABLE vaccines **CANNOT** be returned. Please call KVP. Do not return syringes with needles, broken vials, or opened multi dose vials. If you have vaccines that have been in flood water, please write this across the top of the form and double bag the wet vaccine doses. Remove expired, wasted or spoiled vaccines from the refrigerator/freezer.

If you are returning expired/wasted vaccines, keep one copy of the R&A form for your records, fax one to KVP, and send one with the vaccines being returned. KVP will contact McKesson to send you a return label once we receive your R&A. This process can take up to three weeks. You may use any container you wish to send the expired vaccine back. Do not send gel or ice packs with returned vaccine. Give the container to the UPS driver the next time they are in your clinic. **If you call for a pick up, McKesson will charge you.** If UPS does not come to your clinic and you need a pick up scheduled, notify KVP at (502) 564-4478 or dph.kyp@ky.gov and we will have a pick up scheduled for you.

1. Please **completely** fill out the top section with your clinic's PIN#, phone number, date, clinic name and complete address, and name of person completing the form. Write in the word "adult" or "VFC".
2. List the vaccine name, NDC#, lot number, expiration date and number of doses for each vaccine reported.
3. Use the charts below to find the cost per dose of the vaccine reported and record it in the Cost per Dose section.
4. Multiply the number of doses reported by the cost per dose and enter the amount in the Total Cost section. This represents the dollar amount of the vaccine effected. This is KVP cost. **If KVP requires replacement of the vaccine, it will be a dose per dose replacement, not a cost replacement.** This total is for reference only.
5. Use the chart below to select the code appropriate for the vaccine adjustment.
6. Use the explanation line to give a short description of why the vaccine adjustment occurred. This will be used to determine if a Plan of Correction or Dose Replacement is necessary.
7. **DO NOT SHIP VACCINE TO KVP.**

PLEASE SELECT ADJUSTMENT CODES AND VACCINE COST FROM TABLES BELOW. FAX COMPLETED FORM TO KVP AT 502-696-4923 or dph.kvp@ky.gov. PLEASE KEEP ONE COPY FOR YOUR RECORDS AND SEND ONE COPY WITH VACCINES TO BE RETURNED.

VACCINE PRICES						ADJUSTMENT CODES
PEDIATRIC PRICES				ADULT PRICES		**Code "R" for RETURN:** Vaccine that spoiled or expired in its original vial or syringe. Unused prefilled syringes from manufactureres with an NDC printed on them.
		MENVEO®	$82.12	HAVRIX®	$21.59	
DAPTACEL®	$15.00	M-M-R®II	$19.33	TWINRIX ®	$45.11	
INFANRIX®	$15.35	Prevnar 13®	$102.03	ENGERIX-B	$25.43	
KINRIX®	$35.50	PNEUMOVAX®23	$37.99	GARDASIL®	$92.46	
PEDIARIX®	$52.10	RotaTeq	$61.53	M-M-R®II	$37.17	**Code "W" for Wasted:** Opened multi doses vials, syringes you filled and did not use, any used syringes, broken vials. These items should NEVER be returned to McKesson but must be taken out of your inventory.
Pentacel®	$54.50	ROTARIX®	$91.02	PNEUMOVAX®23	$24.25	
IPOL®	$12.24	DECAVAC®	$16.50	Adacel® *	$24.01	
COMVAX®	$30.20	Td Mass Biologics	$15.00	BOOSTRIX®	$24.96	
VAQTA®	$14.75	BOOSTRIX®	$30.68	VARIVAX®	$60.88	
HAVRIX®	$14.79	Adacel®	$30.41	ZOSTAVAX®	$114.24	
ENGERIX-B	$10.73	VARIVAX®	$72.49	DECAVAC®*	$13.82	**Code "T" for Transfer:** Vaccine that will be transferred to another KVP provider clinic. Vaccine must have been stored properly and have good expiration dates. Other provider & KVP must have approved prior to transfer.
RECOMBIVAX HB®	$10.75	ProQuad®*	$85.72	Menactra®*	$72.49	
PedvaxHIB®	$11.97	FLUZONE®	$9.30	MENVEO®	$68.02	
ActHIB®	$9.20	FLUZONE® PF.25	$11.68	FLUZONE®	$8.15	
HIBERIX®	$8.98	FLUZONE® PF.5	$10.95	FLUZONE® PF.5	$9.55	
GARDASIL®	$111.96	FLUARIX®	$9.25	FLUARIX®	$8.38	
Menactra®	$82.12	FLUVIRIN®	$9.25	FLUVIRIN®	$10.70	prices as of 8/10/12
		FluMist®	$16.50			* last known price

NONVIABLE VACCINE RETURNS

What NOT to Return to McKesson

The following items should *NEVER* be returned to McKesson:

- Syringes that you filled yourself but did not use.
- Any used syringes with or without needles attached.
- Broken vials.
- Any multidose vial from which some doses have already been withdrawn.

The items listed above should be disposed of according to usual medical biosafety procedures, and according to your immunization program's procedures.

What Should be Returned to McKesson

The following items should be returned to McKesson:

- Spoiled or expired product in its original vial or pre-filled syringe.
- Unused pre-filled syringes from manufacturers with an NDC printed on them.

Unused Novartis Fluvirin pre-filled syringes with staked needles (NDC 66521-0112-02) are the ONLY items that can be returned with a needle. The needle should be capped and the syringes returned in their original packaging to the extent possible. (Absolutely no other needle can be returned to McKesson.)

Federal excise tax (FET) credits can only be processed for unopened vials and for unopened manufacturer pre-filled syringes. Returns of product other than these are not eligible for FET credit and should not be returned.

Vaccine Storage

Stand-alone Freezer and Refrigerator-only Units

1. Proper Temperatures

Freeze MMR, MMRV, and Varicella

Aim for 0° F

5° F or below

(-15° C or below)

Don't let temps get too warm!

Refrigerate all other vaccines

Aim for 40° F

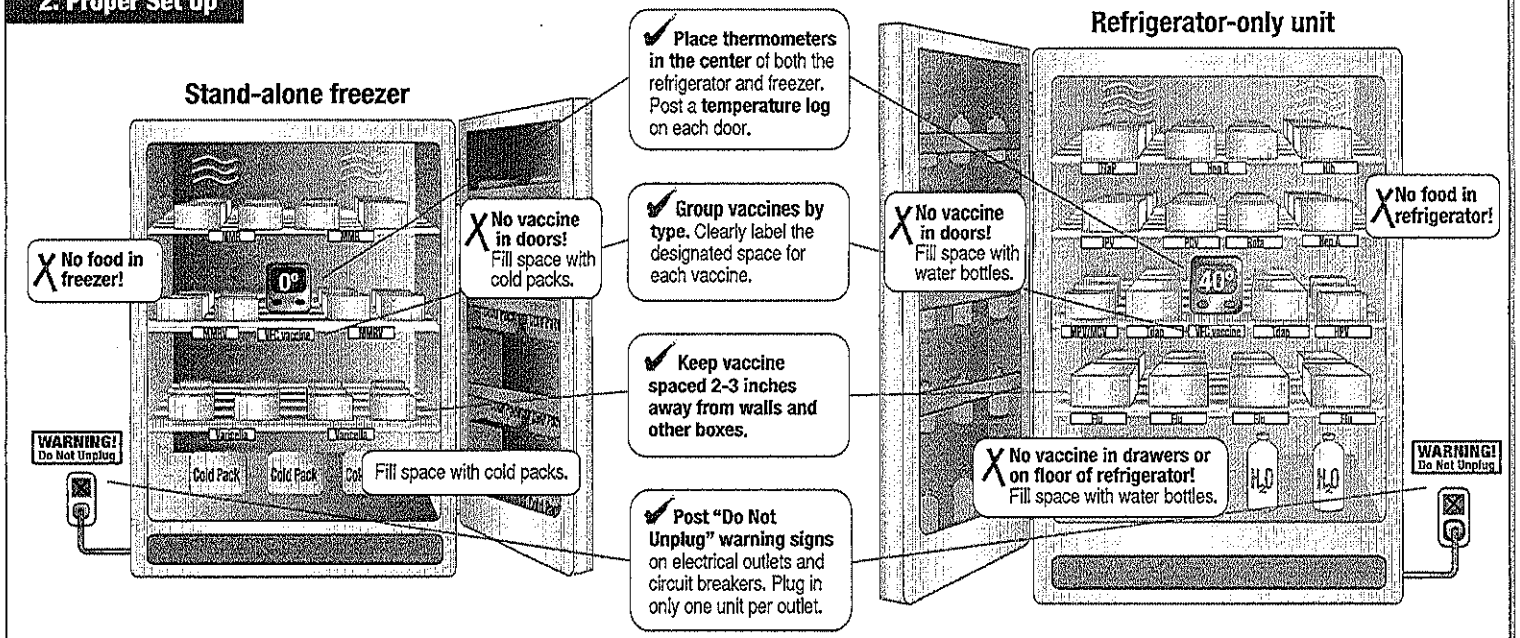
Don't freeze liquid vaccines!

35°F - 46°F

(2°C – 8°C)

Don't let temps get too warm!

2. Proper Set Up



3. Proper Management

Monitor temperatures!

- Use only **certified thermometers** in accordance with National Institute of Standards and Technology (NIST). If your thermometer uses batteries, replace them every 6 months.
- Check and record refrigerator and freezer temperatures twice a day, first thing in the morning and last thing at the close of business. VFC temperature logs must be kept for a period of 3 years. **If the temperature is out of range, immediately contact the VFC Program.**
- Make sure that the door is shut.

Maintain and rotate stock!

- Rotate vaccine stock by placing shorter expiration dates in front. Call VFC if you have any vaccine that will expire within 3 months.
- **Keep vaccines in original packaging until it is time to use it.**
- **Keep VFC vaccines separate from privately purchased vaccines.**
- Have an emergency plan for extended power outages and freezer or refrigerator malfunctions.
- Designate one fully trained staff member to be the primary vaccine coordinator and at least one person to be back-up. Ensure ongoing training.

Call VFC about any problems!

If you have any problems with your refrigerator or freezer:

- Keep the refrigerator and freezer doors shut
- Notify the VFC Program

Vaccines for Children Program (877) 243-8832

VFC Field Representative

VACCINES for CHILDREN CALIFORNIA

Set UP for Success!

Vaccine Storage

Combination Refrigerator/Freezer

1. Proper Temperatures

Freeze MMR, MMRV, and Varicella.

Aim for 0° F

5° F or below
(-15° C or below)

Don't let temps get too warm!

Refrigerate all other vaccines.

Aim for 40° F

Don't freeze liquid vaccines!

35°F - 46°F
(2°C - 8°C)

Don't let temps get too warm!

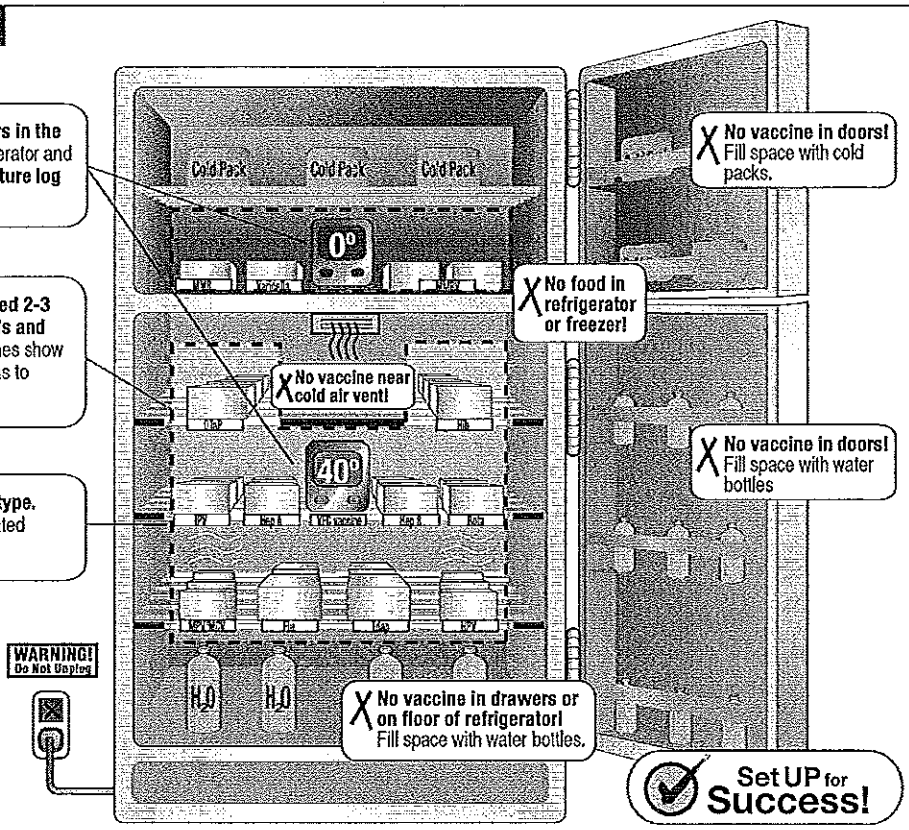
2. Proper Set Up

✔ **Place thermometers in the center** of both the refrigerator and freezer. Post a **temperature log** on the door.

✔ **Keep vaccine spaced 2-3 inches away from walls and other boxes.** Dashed lines show usable space. Mark areas to avoid.

✔ **Group vaccines by type.** Clearly label the designated space for each vaccine.

✔ **Post "Do Not Unplug" warning signs** on electrical outlets and circuit breakers. Plug in only one unit per outlet.



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Monitor capacity–especially during flu season!

- Combination units are acceptable for the storage of minimal quantities of vaccine as long as vaccines are always stored properly within usable space. **New VFC providers and providers receiving more than 2,000 doses of vaccine annually may not use combination units.** Check with your VFC representative for specific criteria.
- Inventory vaccine and ensure that there is enough space in refrigerator and freezer before ordering.

Maintain and rotate stock!

- Rotate vaccine stock by placing shorter expiration dates in front. Call VFC if you have any vaccine that will expire within 3 months.
- **Keep vaccines in original packaging until it is time to use it.**
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Vaccines for Children Program **(877) 243-8832**

VFC Field Representative

3 EASY STEPS TO BUY A REFRIGERATOR OR FREEZER

1 Estimate the maximum number of doses of VFC vaccine and privately purchased vaccine that will be in your refrigerator and freezer.

Refrigerator:

Add the number of doses *on hand (current inventory)* from your last order form.

VFC vaccine	_____
VFC flu vaccine	+_____
Private vaccine	+_____
Private flu vaccine	+_____
Total doses	=_____
Multiply (max inventory)	x 1.25
Maximum doses	=_____

Freezer:

Add the number of doses *on hand (current inventory)* from your last order form.

VFC MMR & Varicella vaccine	_____
Private MMR & Varicella vaccine	+_____
Total doses	=_____
Multiply (max inventory)	x 1.25
Maximum doses	=_____

2 Match your maximum doses with the minimum cubic feet (needed to safely store your vaccine) to find product example. *Indicates pharmacy grade.

Max. Doses	Minimum Cubic Ft.	Examples of Refrigerator–only units
2,000+ doses	may need more than one refrigerator	*See below*
1000 – 2000	40 cu. ft	**Revco** REL-4504A; REL-4504D* **Nor-Lake** NSPR482* **Sanyo** SPR-49GD-MED*
900 – 1000	36 cu. ft.	**Sanyo** MPR-1013; MPR-1013R* **Turbo Air** GST-40DR*
801 - 900	21 - 23 cu. ft	**Aegis Scientific** 1-R-22* **Sanyo** SRR-23FD; SRR-23GD; SRR-23FD*
701 - 800	17 - 19.5 cu. ft.	**Aegis Scientific** 3-CR-17* **Frigidaire** FCGM201RF; FCRS201RFB **Marvel Scientific** 17CAR
400 – 700	11 - 16.7 cu. ft.	**Avanti** BCAD680 **Nor-Lake** LR161WWW/0* **Kenmore** 60722 **Frigidaire** FRU17B2J; FRU17B2JW*
100 - 399	4.9 - 6.1 cu. ft. (Must be pharmacy grade)	**Sanyo** SR-L4110W; SF-L6111W; MPR-214F* **Nor-Lake** LR061WWW/0; NSLR051WMW/0* **Revco** REL-404A*

Max. Doses	Minimum Cubic Ft.	Examples of Freezers–only units
501 – 6,000	7 - 14.8 cu. ft	**Arctic Air** CF07 **Whirlpool** EH150FXR; EH151FXRQ **Frigidaire** AFFC1466DW
201 - 500	5 - 5.6 cu. ft.	**Revco** ULT-430A* **Frigidaire** FFC0522DW **Kenmore** 28502
0 - 200	3.5 - 4.9 cu. ft.	**Nor-Lake** LF041WWW/OM* **Barnstead International Model** 3752 **Revco** ULT-430A*

3 Search for product name and model numbers on the Internet for prices, dimensions, and locations. Verify that the specifications meet all requirements.

Things to think about before buying a refrigerator or freezer:

1. Where will it go?
   - It must be placed away from direct sunlight and in a well ventilated area.
   - There must be enough space around it to allow air to flow freely.
   - There must be an electric outlet nearby that can be used only by the refrigerator and does not depend on the light switch.
2. What is the warranty and extended service option?
3. Will the store dispose of or recycle your old unit?
4. Is there an energy rebate?
5. How long will it take for the delivery of it?

Getting started with a new refrigerator or freezer:

1. Plug in the refrigerator or freezer (one unit per outlet).
2. Place thermometers in the center of unit.
3. Set temperatures to correct ranges:
   Freezer: 0° F
   Refrigerator: 40° F
4. Record temperatures twice a day on your vaccine Temperature Log.
5. Place vaccines in unit if recorded temperatures are within the correct range for at least 5 days in a row.
6. Review Storage Guide at www.eziz.org for proper set- up and storage of vaccines.

Note: *The use of trade names and commercial sources in this document is for identification only, and does not imply endorsement by the California Department of Public Health or the California Vaccines for Children Program. Compare products to the requirements on the front page before purchase, as product availability and features may change.*